

NEW ZEALAND CONSUMER MEDICINE INFORMATION

BETA

Betamethasone valerate cream 0.1% w/w
Betamethasone valerate ointment 0.1% w/w



What is in this leaflet

This leaflet answers some common questions about BETA Cream and Ointment.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using BETA Cream or Ointment against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What BETA Cream or Ointment is used for

Your BETA Cream or Ointment contains the active ingredient betamethasone valerate. It belongs to a group of medicines known as topical corticosteroids. "Topical" means that they are applied onto the skin. Topical corticosteroids are used to help reduce the inflammation that causes the redness and itchiness in a variety of conditions (they are not 'anabolic' steroids which are sometimes misused by athletes).

BETA Cream or Ointment is useful in treating various inflamed conditions of the skin such as:

- psoriasis
- severe forms of eczema
- lichen planus (chronic itchy skin of unknown origin)

- discoid lupus erythematosus (recurring scaly rash)
- prickly heat skin reaction
- insect bite reactions
- prurigo nodularis (an itching and thickening of the skin with lumps or nodules)
- contact sensitivity reactions
- an additional treatment for an intense widespread reddening and inflammation of the skin,

when milder topical corticosteroids cannot treat the skin condition effectively.

BETA Cream is usually used to treat skin conditions on moist surfaces; BETA Ointment is usually used to treat skin conditions on dry, scaly skin.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that BETA Cream or Ointment is addictive.

Before you use BETA Cream or Ointment

When you must not use it:

Do not use BETA Cream or Ointment if you have an allergy to:

- any medicine containing betamethasone valerate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use BETA Cream or Ointment to treat any of the following skin problems as it could make them worse:

- infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
- acne
- rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red, with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules))
- rashes around the mouth
- itchy skin which is not inflamed
- itching around the anus or genitals (penis or vagina).

If your doctor advises the use of BETA Cream or Ointment to treat one of the above skin complications, it is important you follow your doctor's instructions carefully.

Do not use BETA Cream or Ointment on a child under the age of 1 year.

Safety and effectiveness in children younger than 1 year old have not been established.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you do use BETA Cream or Ointment when breast-feeding, do not use on your breast area so that the baby does not accidentally get the medicine in their mouth.

If you have not told your doctor about any of the above, tell him/her before you start using BETA Cream or Ointment.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and BETA Cream or Ointment may interfere with each other. These include:

- ritonavir (a medicine used for the treatment of HIV)
- itraconazole (a medicine for the treatment of fungal infections).

These medicines may be affected by BETA Cream or Ointment or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use BETA Cream or Ointment

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to use

Use only enough BETA Cream or Ointment to cover the entire affected area once or twice a day.

It is important that you only apply BETA Cream or Ointment exactly as directed by your doctor. **Do not use more than the recommended amount.**

Sometimes repeated short courses of BETA CREAM or OINTMENT may be used to control your skin condition. **Your doctor may tell you to use a different amount. If so, it is important you follow their instructions carefully.**

How to use it

Apply a thin layer once or twice daily and gently rub in, using only enough to cover the entire affected area.

Wash your hands after use unless treating the hands.

If you are also using an emollient or moisturising preparation, allow time for BETA Cream or Ointment to be absorbed after each application before applying the emollient.

If your eczema flares up frequently, your doctor may suggest that you use a less frequent dose of BETA Cream or Ointment once your eczema is under control, to stop your eczema from coming back.

When to use it

Use BETA Cream or Ointment at about the same time each day. Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it

BETA Cream or Ointment should be used once or twice daily for no more than four weeks at a time.

Do not use BETA Cream or Ointment for any longer than

your doctor has prescribed. If the condition worsens or does not improve within two to four weeks, talk to your doctor or pharmacist.

If you forget to use it

If you forget to use BETA Cream or Ointment apply it as soon as you remember then continue as before.

Do not apply extra BETA Cream or Ointment to make up for a missed dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have accidentally swallowed BETA Cream or Ointment; or if you or anyone else may have used too much BETA Cream or Ointment. **Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

While you are using BETA Cream or Ointment

Things you must do

Tell your doctor if, for any reason, you have not used your medicine exactly as directed. Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using BETA Cream or Ointment.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have any blood tests, tell your doctor that you are using BETA Cream or Ointment.

If you become pregnant while using this medicine, tell your doctor immediately.

Things you must not do

Do not use BETA Cream or Ointment on children under 1 year of age.

Do not use BETA Cream or Ointment to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine without checking with your doctor.

If you use BETA Cream or Ointment regularly make sure you talk to your doctor before you stop using it.

Do not let BETA Cream or Ointment get into your eyes.

If the medicine does accidentally enter your eyes, rinse your eye(s) thoroughly with water. Do not touch your eyes until you have washed your hands.

Things to be careful of

Take care when applying BETA Cream or Ointment to the eyelids to make sure it does not get into your eye.

Take care when applying BETA Cream or Ointment to the face over a long period of time as it may cause skin thinning.

If you have eczema around a leg ulcer, use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.

Only use an airtight dressing over this medicine if your doctor has told you to.

If you are applying BETA Cream or Ointment under an airtight dressing, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using BETA Cream or Ointment.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin rash
- hot burning sensation
- itching.

Tell your doctor as soon as possible if you notice any of the following:

- thinning of the skin and appearance of stretch marks
- changes to the colour of your skin
- increase in hair growth
- appearance of blood vessels under the surface of your skin.
- blurred vision.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- if your skin condition gets worse or your skin becomes swollen during treatment, you may be allergic to the medicine, have an infection or need other treatment
- wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Use of BETA Cream or Ointment for a long period of time, or use under an airtight dressing, may cause the following symptoms:

- increased weight
- moon face / rounding of the face
- obesity
- skin thinning, this may cause stretch marks
- skin wrinkling
- skin dryness
- the appearance of blood vessels under the surface of your skin
- increased body hair
- hair loss / lack of hair growth / damaged looking hair.

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- irritation at the site of application
- redness
- rash or hives
- skin infection
- if you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some very rare side effects can only be found when your doctor does blood tests or a medical examination:

- decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)

- a weakening of the bones through gradual loss of mineral (osteoporosis). Additional tests may be needed after your medical examination to confirm if you have this condition.

After using BETA Cream or Ointment

Storage

Keep your BETA Cream or Ointment in the tube until it is time to use it.

Keep your BETA cream or ointment in a cool dry place where the temperature stays below 25°C.

Do not store BETA Cream or Ointment or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Both BETA Cream and Ointment are white in colour.

Ingredients

BETA Cream and BETA Ointment each contain 0.1% w/w of betamethasone as the active ingredient.

BETA Cream also contains:

- white soft paraffin
- cetostearyl alcohol
- liquid paraffin

- cetareth 20
- sodium phosphate monobasic
- chlorocresol
- sodium hydroxide
- purified water.

BETA Ointment also contains:

- white soft paraffin
- white beeswax
- propylene glycol
- stearyl alcohol.

BETA Cream and BETA Ointment do not contain lanolin or parabens.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of Information

16 January 2019 (Based on datasheet dated 16 January 2019)